



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 18 2009

Re: DORIBAX
Docket No. FDA-2008-E-0266

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,317,016 filed by Shionogi Seiyaku Kabushiki Kaisha, under 35 U.S.C. § 156. The human drug product claimed by the patent is DORIBAX (doripenem monohydrate), which was assigned new drug application (NDA) No. 22-106.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on October 12, 2007, which makes the submission of the patent term extension application on December 4, 2007, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad", is positioned above the typed name.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

Dudas - DORIBAX
Patent No. 5,317,016
Page 2

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